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Fran Ideker	Fran Ideker
Name of person mailing paper and fee	Signature of person mailing paper and fee

VENTRICULAR RESTORATION SHAPING APPARATUS AND METHOD OF USE

Inventors: Gregory Murphy
2502 Overcreek Dr.
Richardson, TX 75080
Citizenship: USA

Suresh Reddy
3201 Tam O'Shanter
Richardson, Texas 75080
CITIZENSHIP: India

Albert Davis
304 Arborcrest
Richardson, Texas 75080
CITIZENSHIP: USA

Assignee: Chase Medical, LP
1710 Firman Drive
Suite 100
Richardson, Texas 75081

HAYNES AND BOONE, L.L.P.
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
(214) 651-5000

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VENTRICULAR RESTORATION SHAPING APPARATUS AND METHOD OF USE

CROSS-REFERENCE

[0001] This invention claims the benefit of U.S. Provisional Patent Application Serial No. 60/272,073 filed on February 28, 2001.

TECHNICAL FIELD

[0002] This invention relates generally to surgical methods and apparatus for addressing cardiomyopathy, and more specifically to methods and apparatus for restoring the architecture and normal function of a mammalian heart.

BACKGROUND

[0003] The function of a heart in an animal is primarily to deliver life-supporting oxygenated blood to tissue throughout the body. This function is accomplished in four stages, each relating to a particular chamber of the heart. Initially deoxygenated blood is received in the right auricle of the heart. This deoxygenated blood is pumped by the right ventricle of the heart to the lungs where the blood is oxygenated. The oxygenated blood is initially received in the left auricle of the heart and ultimately pumped by the left ventricle of the heart throughout the body. It can be seen that the left ventricular chamber of the heart is of particular importance in this process as it is relied upon to pump the oxygenated blood initially through an aortic valve into and ultimately throughout the entire vascular system.

[0004] The amount of blood pumped from the left ventricle divided by the amount of blood available to be pumped is referred to as the ejection fraction of the heart. Generally, the higher the ejection fraction the more healthy the heart. A normal heart, for example may have a total volume of one hundred milliliters and an ejection fraction of 60 percent. Under these circumstances, 60 milliliters of blood are pumped with each beat of the heart. It is this volume in the normal heart of this example that is pumped with each beat to provide nutrients including oxygen to the muscles and other tissues of the body.

[0005] The heart is part of the body tissue, and the heart muscle also requires oxygenated blood. Its normal function is greatly upset by clotting or closure of the coronary arteries. When the coronary arteries are blocked, an associate portion of the heart muscle becomes oxygen-starved and begins to die. This is clinically referred to as a heart attack. Ischemic cardiomyopathy typically occurs as the rest of the heart dilates in an attempt to maintain the heart's output to the body.

[0006] As the ischemia progresses through its various stages, the affected myocardium dies losing its ability to contribute to the pumping action of the heart. The ischemic muscle is no longer capable of contracting so it cannot contribute to either squeezing or twisting motion required to pump blood. This non-contracting tissue is said to be "akinetic." In severe cases the akinetic tissue, which is not capable of contracting, is elastic so that blood pressure tends to develop a bulge or expansion of the chamber. In this situation, this muscle tissue is not only akinetic, in that it does not contribute to the pumping function, but it is in fact "dyskinetic," in that it detracts from the pumping function. This situation is particularly detrimental as the heart loses even more of its energy due to pumping the blood to the bulge instead of through the aorta.

[0007] After a heart attack, the body seems to realize that with a reduced pumping capacity, the ejection fraction of the heart is automatically reduced. For example, the ejection fraction may drop from a normal 60 percent to 20 percent. Realizing that the body still requires the same volume of blood for oxygen and nutrition, the body causes its heart to dilate or enlarge in size so that the smaller ejection fraction pumps about the same amount of blood. As noted, a normal heart with a blood capacity of seventy milliliters and an ejection fraction of 60 percent would pump approximately 42 milliliters per beat. The

body seems to appreciate that this same volume per beat can be maintained by an ejection fraction of only 30 percent if the ventricle enlarges to a capacity of 140 milliliters. This increase in volume, commonly referred to as “remodeling”, not only changes the volume of the left ventricle, but also its shape. The heart becomes greatly enlarged. An enlarged heart will tend to change its architecture from the normal conical or apical shape, to a generally spherical shape.

[0008] On the level of the muscle fibers, it has been noted that enlargement or dilation of the heart causes the fibers to reorient themselves so that they are directed away from the inner heart chamber containing the blood. As a consequence, the fibers are poorly oriented to accomplish even the squeezing action, as the lines of force become less perpendicular to the heart wall. This change in fiber orientation occurs as the heart dilates and moves from its normal elliptical shape to its dilated spherical shape. The spherical shape further reduces pumping efficiency since the fibers which normally encircle the apex to facilitate writhing are changed to a more flattened formation as a result of these spherical configurations. The resulting orientation of these fibers produces lines of force, which are also directed laterally of the ventricle chamber. Thus, the dilation and resulting spherical configuration greatly reduces contraction efficiency.

[0009] Perhaps the most notable symptom of ischemic cardiomyopathy is the reduction in the ejection fraction which may diminish, for example, from a normal 60 percent to only 20 percent. This results clinically in fatigue and in an inability to do stressful activities that require an increase in output of blood from the heart. The output of blood by the enlarged heart at rest is kept normal, but the capacity to increase output of blood during stress (i.e., exercise, walking) is significantly reduced. Of course, the change in architecture has a dramatic effect on wall thickness, radius, and stress on the heart wall. In particular, it will be noted that absent the normal conical shape, the twisting motion of the heart, which can account for as much as one half of the pumping action, is lost. As a consequence, the more spherical architecture must rely almost totally on the lateral squeezing action to pump blood. This lateral squeezing action is inefficient and very different from the more efficient twisting action of the heart. The change in architecture of the heart will also typically change the structure and ability of the mitral valve to perform its function in the pumping

process. Valvular insufficiency can also occur due to dilatation.

[0010] Although the dilated heart may be capable of sustaining life, it is significantly stressed and rapidly approaches a stage where it can no longer pump blood effectively. In this stage, commonly referred to as congestive heart failure, the heart becomes distended and is generally incapable of pumping blood returning from the lungs. This further results in lung congestion and fatigue. Congestive heart failure is a major cause of death and disability in the United States with approximately 400,000 new cases annually.

[0011] Following coronary occlusion, successful acute reprefusion by thrombolysis, (clot dissolution) percutaneous angioplasty, or urgent surgery can decrease early mortality by reducing arrhythmias and cardiogenic shock. It is also known that addressing ischemic cardiomyopathy in the acute phase, for example with reperfusion, may salvage the epicardial surface. Although the myocardium may be rendered akinetic, at least it is not dyskinetic. Post-infarction surgical re-vascularation can be directed at remote viable muscle to reduce ischemia. However, it does not address the anatomical consequences of the akinetic region of the heart that is scarred. Despite these techniques for monitoring ischemia, cardiac dilation and subsequent heart failure continue to occur in approximately 50 percent of post-infraction patients discharged from the hospital.

[0012] Various surgical approaches have been tried to treat the dilation of the ventricle by primarily reducing the ventricular volume. Some of these procedures involve removing or excluding dyskinetic and akinetic regions of the heart, then surgically joining the viable portions of the myocardial walls, typically with the use of a patch surgically placed in the walls using a Fontan stitch.

[0013] Typically, the exact placement of the patch has been visually determined using only a visual indication where the typically white scar tissue meets the typically red normal tissue. Location of the patch has been facilitated in a further procedure where a continuous suture has been placed around the ventricular wall to define a neck for receiving the patch. The neck has been formed in the white scar tissue rather than the soft viable muscle. This procedure has relied on cardioplegia methods to stop the beating of the heart and to aid in suture placement.

[0014] These surgical procedures have been met with some success as the ejection fraction has been increased, for example, from 24 percent to 42 percent. However, despite this level of success, it is often difficult for the surgeon to reconstruct the shape and size of the left ventricle. If the reconstructed ventricle is too small, the patient will not be able to pump enough oxygenated blood. If the reconstructed ventricle is too large, the ejection fraction may diminish. In addition to the size, the shape of the reconstructed ventricle is also important. If the left ventricle is reconstructed in a spherical shape, a twisting motion of the heart about its apex, which can account for as much as one half of the pumping action, is lost. As a consequence, the spherical shaped reconstructed ventricle must rely almost totally on the lateral squeezing action to pump blood. This lateral squeezing action is inefficient and very different from the more efficient twisting action of the heart. What is needed, therefore is a reliable method and apparatus to allow a surgeon to reconstruct the left ventricle to the appropriate shape, size and contour.

SUMMARY

[0015] In response to these and other problems, an improved apparatus and method is provided for restoring the geometry of the left ventricle to counteract the effects of cardiac remodeling. One embodiment of the present invention provides an apparatus and method to reconstruct an enlarged left ventricle of a human heart, using a shaper, having a size and shape substantially equal to the size and shape of an appropriate left ventricle, wherein the shaper is adapted to be temporarily placed into the enlarged left ventricle during a surgical procedure. Another aspect of one embodiment comprises a ventricular patch adapted for placement into the left ventricle of a heart made from a sheet of biocompatible material, and having a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch. In another aspect of one embodiment, a device is presented, comprising of a handle and a sizing template adapted to be coupled to the handle. Such components are also presented as a kit for use during ventricular restoration surgery.

BRIEF DESCRIPTION OF THE FIGURES

[0016] Fig. 1 illustrates one embodiment of a process utilizing several aspects of the

present invention.

[0017] Fig. 2a is a side view of one embodiment of a shaping device.

[0018] Fig. 2b is a side view of a balloon embodiment of a shaping device.

[0019] Fig. 2c is a section view of another balloon embodiment of a shaping device.

[0020] Fig. 2d is a section view of another balloon embodiment of a shaping device.

[0021] Fig. 2e is a section view of another balloon embodiment of a shaping device.

[0022] Fig. 2f is a section view of another balloon embodiment of a shaping device.

[0023] Fig. 2g is a side view of a wire frame embodiment of a shaping device in an expanded condition.

[0024] Fig. 2h is a side view of a wire frame embodiment of a shaping device in an expanded condition.

[0025] Fig. 2j is a section view cut transversely through the embodiment of Fig. 2h.

[0026] Fig. 3a is a top view of one embodiment of a patch.

[0027] Fig. 3b is a top view of one embodiment of markings which may be coupled to the patch of Fig. 3a.

[0028] Fig. 3c is a top view of one embodiment of markings which may be coupled to the patch of Fig. 3a.

[0029] Fig. 3d is a top view of one embodiment of markings which may be coupled to the patch of Fig. 3a.

[0030] Fig. 3e is a top view of one embodiment of markings which may be coupled to the patch of Fig. 3a.

[0031] Fig. 4a is a top view of one embodiment of a set of sizers.

[0032] Fig. 4b is a top view of one embodiment of a handle to be used with the set of sizers illustrated in Fig. 4a.

[0033] Fig. 4c is a detailed section view illustrating a connection between the handle and a sizer.

[0034] Fig. 4d is a section view of one embodiment of a sizer.

[0035] Fig. 4e is a section view of one embodiment of a sizer.

[0036] Fig. 4f is a section view of one embodiment of a sizer.

[0037] Fig. 4g is a top view of one embodiment of a sizer made of malleable wire.

[0038] Fig. 4h is a side view of the sizer illustrated in Fig. 4g.

[0039] Fig. 5a is a top view of one embodiment of a patch holder.

[0040] Fig. 5b is a top view of one embodiment of a suture hook.

[0041] Fig. 6 is a top view of one embodiment of a kit for surgically reshaping a ventricle.

[0042] Fig. 7a illustrates one embodiment of a process utilizing several aspects of the present invention.

[0043] Fig. 7b is a continuation of the process illustrated in Fig. 7a.

DETAILED DESCRIPTION:

[0044] An overview method of one embodiment is presented which introduces the primary components of one embodiment. A detailed discussion of these components then follows. Finally, a method of using the components is discussed in detail.

OVERVIEW:

[0045] Turning to Fig. 1, there is presented an overview method 100 for performing and using one embodiment of the present invention. A more complete discussion of this method will be presented below. The method 100 may use the following components: a shaping device 200 (Fig. 2a), a patch 300 (Fig. 3a), a sizer 402a (Fig. 4a), and a suture hook 520 (Fig. 5). Referring back to Fig. 1, at step 102, a surgeon determines the appropriate size for the patient's left ventricle based on the patient's height, weight, body surface area and other patient specific conditions. Once the patient's appropriate ventricle size has been determined, at step 104, the surgeon can then select the appropriate volume for the shaping device 200. At step 106, the surgeon opens up the chest cavity in a conventional manner. An incision is cut into the myocardial wall of an enlarged heart in step 108. At step 110, the surgeon may remove all or some of the non-viable tissue (i.e.,

the dyskentic and akinetic areas) of the myocardium. A continuous round stitch, known in the art as a Fontan stitch, may then be woven into the ventricle, at step 114. The stitch produces an annular protrusion, which forms an opening. At step 116, the shaping device 200 may be inserted into the ventricle through this opening. The musculature of the myocardium may be pulled over the shaping device to form a left ventricle having a predetermined volume, shape and contour. The shaping device 200 may then be compressed and removed at step 120. At step 122, with the aid of the sizer 402a, the surgeon may determine the preferred location of and size of the patch 300 which may be placed in the left ventricle. The patch 300 is then cut to size in step 124 and secured to the inside of the myocardium in step 126. At step 128, with the patch 300 suitably placed, the ventricle is closed by joining the myocardial walls over the patch.

DESCRIPTION OF COMPONENTS:

The Shaping Device:

[0046] Fig. 2a illustrates one embodiment of a shaping device 200. In an inflated condition, the shaping device 200 is pre-shaped to generally model the appropriate volume and shape of the left ventricle.

[0047] The shape of the normal heart is of particular interest as it dramatically affects the way that the blood is pumped. The left ventricle which is the primary pumping chamber, is somewhat conical or apical in shape in that it is longer (long axis longest portion from aortic valve to apex) than it is wide (short axis widest portion from ventricle wall to septum) and descends from a base with a decreasing cross-sectional circumference to a point or apex. The left ventricle is further defined by a lateral and posterior ventricle wall and a septum, which extends between the auricles and the ventricles. The pumping of the blood from the left ventricle is accomplished by two types of motion. One of these motions is a simple squeezing motion, which occurs between the lateral wall and the septum. The squeezing motion occurs as a result of a thickening of the muscle fibers in the myocardium. This compresses the blood in the ventricle chamber and ejects it into the body. The thickness changes as the ventricle contracts. This is seen easily by

echocardiogram and can be routinely measured.

[0048] The other type of motion is a twisting or writhing motion, which begins at the apex and rises toward the base. The rising writhing motion occurs because the heart muscle fibers run in a circular or spiral direction around the heart. When these fibers constrict, they cause the heart to twist initially at the small area of the apex, but progressively and ultimately to the wide area of the base. These squeezing and twisting motions are equally important, as they are each responsible for moving approximately one-half of the blood pumped. Turning now to Fig. 2a., there is shown a shaping device 200 that allows the left ventricle to be reconstructed back to a pre-enlarged operating condition. When the surgeon uses shaping device 200 as a guide in reconstructing the left ventricle, the reconstructed heart can be formed closer to the size and shape of the pre-enlarged heart. Consequently, the heart performs better post operatively than with conventional methods. As illustrated, the shaping device 200 is generally conical or "tear drop" in shape. The length "L" of the shaping device 200 may vary with each patient and will typically be a function of the volume selected for the shaping device. Depending on the patient, the length "L" may be in the three to four inch range to generally match the length of the pre-enlarged left ventricle. A surgeon may select the appropriate volume for the shaping device by estimating the volume of the pre-enlarged left ventricle. The appropriate volume of the pre-enlarged left ventricle for a patient may be estimated to be 50 to 70 cc per square meter of body surface area. The body surface area may be estimated according to the following formula; as known in the art:

$$BSA = 0.001*71.84w^{0.428}*h^{0.725}$$

Where: BSA = body surface area,

w = body weight in kilograms, and

h = body height in centimeters.

[0049] The shaping device may be of an "appropriate shape" for a patient. In other words, the shaping device may be of a shape similar to the shape of the left ventricle. In one embodiment, the shaping device 200 may be a generally conical shaped object

composed of portions of spherical elements having different radii. Referring back to Fig. 2a, the illustrative embodiment of the shaping device may be divided lengthwise into six sections where each section is a length "L2" apart. L2, therefore, may be determined from the formula: L2 = .1665*L. At line "A-A", a width W1 of the shaping device 200 is approximately .543*L. The back surface 202 of the shaping device 200 is generally shaped as a portion of a sphere, having a radius of .802*L. At a line "C-C", a width W2 of the shaping device 200 is approximately .628*L. The side surfaces 204a and 204b are combinations of portions of spheres with different radii. Between the line A-A and the line C-C, the side surfaces 204a and 204b have a radius of .515L.

[0050] At a line "E-E", a width W3 of the shaping device 200 is .435*L. Between the line C-C and the line E-E, the side surfaces 204a and 204b have a radius of .945L. The shaping device 200 narrows from the line designated "E-E" through a line designated as "F-F" to a vertex 206 at point "G". It is important to note that the above discussion is illustrative of only one embodiment of the present invention and is not meant to limit the invention to the above ratios or shapes.

[0051] In some embodiments, such as illustrated in Fig. 2b, the shaping device may be an inflatable balloon 201, having a thickness of in the range of .02 to .08 inches, preferably .03 inches. A distal end of a filler tube 208 may be coupled to a point 207 along the exterior surface of balloon 201. For instance, the point 207 could be located approximately 1/3 along balloon's 201 length, as illustrated in Fig. 2b. In other embodiments, the filler tube 208 may be coupled vertex 206. Such tubes are well known in the art, and illustratively may be made of materials such as PVC. A proximal end of the filler tube 208 may be connected to a fluid reservoir, such as a syringe 210 which may inject a pre-specified amount of fluid into the balloon 201 through the filler tube 208. Also coupled to the distal end of the filler tube 208 may be a fluid control device such a stopcock 212. The injection of fluid through the filler tube 208 inflates the balloon 201 to an inflated condition, as illustrated in Fig. 2b. Once inflated, the fluid inside the shaping device may be prevented from escaping by locking the stopcock 212. This allows the balloon 201 to stay inflated with the proper volume, shape and contour during the reconstruction procedure.

[0052] The fluid pressure inside the balloon 201 may also be monitored by a pressure

transducer, such as a piezoelectric transducer (not shown) coupled to the filler tube 208 with a y-connection (not shown). In other words, one lead of the y-connection would be coupled to a pressure monitor, the other lead would be coupled to the fluid source. Alternatively, the pressure monitor could be coupled to a three way stopcock (not shown), which would monitor the pressure on the filler tube side of the three way stopcock.

[0053] The fluid used to fill the balloon 201 may be any one of a number of fluids, such as saline solution or distilled water. Alternatively, another embodiment could use a sealed balloon containing a silicone gel, such as a liquid methyl silicone resin capable of being vulcanized blended with a dimethyl silicone fluid. Such gels are available from Applied Silicon Inc. (Ventura, California). An embodiment using a sealed balloon would not need an external fluid reservoir, such as syringe 210.

[0054] The balloon 201 may be conventionally formed on a mandrel (not shown) having dimensions corresponding to the shape, contour and size of the shaping device. As is known in the art, the mandrel can be made of metal, glass or a hardened gelatin. To form the balloon 201, the mandrel is dipped into a polymer solution, which leaves a thin polymer coating on the mandrel surface. After the polymer has cured, the balloon 201 is removed by peeling the thin coating off the mandrel or by flushing mandrel material out of the shaping device.

<u>Shaping Device – Other Embodiments:</u>

[0055] The shaping device of the present invention may be made out of a variety of materials in a number of configurations creating a number of embodiments. For instance if the shaping device is molded from a thermoplastic polymer such as PVC or polyethylene or a similar material, the balloon may be "non-expandable" when inflated. In other words, once the balloon is inflated, the balloon 201 will not significantly expand beyond the original shape. To illustrate, several shaping devices might have volumes ranging from 100cc to 150cc at 10cc increments. If a surgeon predetermines that a patient's pre-enlarged left ventricle was 128cc., then the surgeon might select a non-expandable balloon having a volume of 130cc. A surgeon could also request a custom non-expandable balloon with a volume specifically sized for an individual patient.

[0056] In contrast, if the balloon 201 is made from an elastomeric material, the balloon 201 may significantly expand. Such elastomeric materials may include latex, polyurethane, silicone, and other elastomers sold under the trade names KRATON (Shell Chemical, New York, N.Y.), C-FLEX (Concept Polymer, Largo, Fla.) and SANTOPRENE (Monsanto, St. Louis, Mo.) Once the balloon is substantially inflated, the influx of additional fluid causes additional expansion of the balloon. Using this embodiment, the surgeon would simply inflate the balloon to a specific volume. The original shape of the balloon may be maintained during this expansion by selectively thickening the walls of the balloon. Fig. 2c is a section view of an embodiment showing thickened walls of an "expandable balloon" 220. An insertion or distal end 222 of the balloon 220 has walls at a maximum thickness. From the line A-A, the wall thickness progressively decreases to a vertex 224 at point G. In some embodiments, the vertex 224 connects to the filler tube 208. The wall thickness will depend on the expansion range of the balloon. For example, for an expansion of 100 to 150 cc, the thickness of the balloon would vary from .01" at a thin end to .05" at the thick end. Thus, this size or volume of this embodiment may be controlled by controlling the amount and pressure of the fluid injected into the balloon 220.

[0057] In another embodiment, the shaping device could have walls that are relatively thick and are coupled to foam spacers or thermoplastic polymer pads surrounding the exterior of the balloon. Turning now to Fig. 2d, there is shown a section view of an embodiment having polymer pads 232a through 232l coupled to the exterior of a balloon 230. In a substantially inflated condition, polymer pads 232a-232l provide a plurality of contact points: "A" through "L". Contact points "A" though "L", if connected, would define a space of approximately the same volume occupied by the balloon 201 (Fig. 2a). Consequently, the balloon 230 would need less fluid for inflation and the polymer pads 232a through 232l would also provide puncture resistance.

[0058] In yet another embodiment, the shaping device could be a balloon within a balloon. Fig. 2e. illustrates such an embodiment. A balloon 250 is generally shown in Fig. 2e. The balloon 250 comprises a outer balloon 252 and an inner balloon 254. In one embodiment, the inner balloon 254 is inflatable with a fluid, such as saline solution fluid. As in other embodiments, the inner balloon 254 may be inflated through the filler tube 208.

A space 256 between the inner balloon 254 and the outer balloon 252 may be pre-filled with a gel 258, such as a silicone gel or saline solution.

[0059] Fig. 2f is a section view illustrating another embodiment of a balloon 260 formed to be puncture resistant. In this embodiment, the wall 262 proximal to the vertex 206 is progressively thickened to protect the proximal side of the balloon 260 from punctures during the reconstruction procedure. In an alternative embodiment, the wall 262 could be coupled to protective pads located around the vertex 206 to protect the balloon 260 from punctures. In yet another embodiment, the balloon could be made from a thick, self sealing latex rubber. Such latex compounds are well known in the industry.

[0060] The shaping device is not limited to polymeric balloon embodiments. Fig. 2g illustrates a shaping device 280 made from a wire skeleton or frame. The wire frame could be made from surgical grade stainless steel, titanium, tantalum, or nitinol, which is a commercially available nickel-titanium alloy material that has shape memory and is superelastic. Nitinol medical products are available from AMF of Reuilly, France, and Flexmedics Corp., of White Bear Lake, Minnesota.

[0061] The shaping device 280 illustrated in Fig. 2g is in an expanded condition. Running through the center of shaping device 280 is a main shaft 282. The main shaft 282 has a distal end 284 and a proximal end 286. At the distal end 284 is a joint 288. Coupled to the joint 288 is a series of back ribs 290a though 290h (only back ribs 290a through 290e are visible in Fig. 2g). Back ribs 290a through 290h are connected to front ribs 292a-292h by hinges 294a though 294h (only front ribs 292a-292e and hinges 294a-294e are visible in Fig. 2f). The proximal end of front ribs 292a through 292e are connected to a collar 296 through a series of hinges (not shown) radially spaced around collar 296. The use of hinges around collar 296 encourages front ribs 292a-292h to form a convex angle with respect to shaft 282 at collar 296.

[0062] Fig. 2h shows the shaping device 280 in a collapsed position. In a collapsed position, back ribs 290a-290h and front ribs 292a-292h surround shaft 282 as illustrated in Fig. 2j. Fig. 2j is a section view cut transversely through shaft 282 and the front ribs 292a-292h. In operation, once the shaping device 280 is inserted into the left ventricle, a surgeon may slide collar 296 along shaft 282 towards distal end 284. The force exerted

on collar 296 will cause the ribs to buckle radially outward as illustrated in Fig. 2g. Eventually, the front ribs 292a-292h will bend under the applied force. Because the front ribs 292a-292h are under stress, they will tend to push the collar 296 towards proximal end 286. A lock 294 prevents any desired movement towards proximal end 286. Thus, the collar 296 is held firmly in place along shaft 282 by the front ribs 292a-292h exerting a force through collar 296 to lock 294. The lock 294 is spring (not shown) activated and is designed such that the collar 296 may easily slide over the lock when moving from the proximal end 286 to the distal end 288. When the surgeon is ready to remove the shaping device 280, the surgeon may collapse the shaping device 280 by pressing down on lock 294 which will allow the collar 296 to slide past the lock 294 towards the proximal end 286.

<u>Patch</u>

[0063] As will be explained in greater detail below, a patch is often used in the ventricle reconstruction procedure. A patch is made from sheet material and may be a variety of shapes, including circular, elliptical, or triangular, preferably sized and configured with a shape similar to a Fontan neck, as discussed below. As illustrated in Fig. 3a, an elliptical patch 300 may have a length between 30 and 50 millimeters along a major axis 302 and a width along a minor axis 304 of between 20 and 30 millimeters. The preferable thickness of the patch is in the range of .3 to .7 mm. The water permeability is preferably less than 5 ml per cm sq. per minute at 120 mm Hg. The burst strength of the patch is preferably 30 to 35 kg/cm^2. Finally, the 45° angle suture retention strength of the patch should be greater than 3 kg.

[0064] The sheet material for the patch 300 may be formed from a biocompatible synthetic material, for example, from polyester, Dacron (Hemoshield) manufactured by the DuPont Corporation, or polytetrafluoroethylene (Gortex). The sheet material may also be autologous pericardium, or some other fixed mammalium tissue such as bovine pericardium or porcine tissue. The biocompatible synthetic material patch may be collagen impregnated to assist in hemostasis, or it may be sprayed with a hemostatic sealant to achieve better and instantaneous hemostasis.

[0065] The patch may have markings that enable the movement and position of the

patch to be post-operatively observed and analyzed under imaging systems, such as Magnetic Resonance Imaging ("MRI"), x-ray machines, fluoroscopy or other external visualization methods, for post-operative clinical evaluation. Such markings will allow identification of the patch and allow for analysis of the heart's contractility in future post-operative evaluations.

[0066] The markings may be radiopaque. Radiopaque markings are made from material that are impenetrable to radiation such as x-rays. Radiopaque markings may be applied to the patch material in a wide variety of methods. For instance, if the patch material is from a woven fabric, then radiopaque threads could be woven into the fabric at regular intervals. Such radiopaque threads could be metal and made from alloys of gold, nitinol, platinum, or stainless steel. Radiopaque threads could also be made of a biocomptabile polymeric material mixed with a metal powder, such as barium sulfate. Radiopaque markings could also be imprinted onto the fabric with radiopaque ink. Such ink is available from Creative Imprints Inc., (Norton, Massachusetts).

[0067] Other techniques for marking the patch 300 might include chemical vapor deposition, physical vapor deposition, electroplating and ion-beam assisted deposition. In ion-beam assisted deposition, an electron beam evaporator is used to create a vapor of atoms that coats the surface of the material.

[0068] Radiopaque threads might interfere with MRI scans because MRI is extremely sensitive to metal and metal can substantially mask MRI signals. However, if metal markings are made sufficiently small, they will show as bands in an MRI scan. Using metal fibers 0.1mm to 0.05mm to create the grid or pattern by weaving into the patch can make a patch MRI sensitive. Also, the metal can be applied to the patch by ion deposition which could deposit a layer of metal 0.01mm thick onto the patch material. Small tubular strands filled with fatty acids could also be used as be used as MRI sensitive markings. Such strands could be woven into the patch material.

[0069] The markings may be Positron Emission Tomography ("PET") sensitive by making the markings slightly radioactive. However, such markings would probably only be useful for a relatively short time frame after the procedure because of radioactive decay.

[0070] The markings may also be attached to the material by a variety of mechanical

means such as sewing or weaving the markings into patch material or using microclips. Similarly, the markings such as metal threads may also be attached to the material by adhesive means, such as a bio-compatible glue. Such bio-compatible glues are available from Bioglue, Cryolife Inc. (Kennesaw, Georgia) or Cyanoacrylate, by Loc Tite Corp.

[0071] In order to be useful, the markings must be arranged in a pattern that allows post operative evaluation. One such pattern is a series of equally spaced substantially parallel lines as illustrated in Fig. 3b. Another pattern is a grid of substantially parallel lines as illustrated in Fig. 3c. The distance between these parallel lines may be in standard units, such as 1 centimeter. Another pattern could be in the form of concentric circles, as illustrated in Fig. 3d. Yet, another pattern could be a series of lines radiating from a single point at, for instance, a set angle apart. Such a pattern is illustrated in Fig. 3e.

<u>Sizers</u>

[0072] Turning now to Fig. 4a, there is illustrated a set of sizers 402a-402d. The sizers 402a-402d are shaped to be the approximate size of the patch 300 (Fig. 3a). Similar to the patch, the sizers 402a-402d will be of various geometries, length and width combinations. For illustrative purposes, the sizers 402a-402d discussed herein will be elliptical in shape. For posterior repairs to the ventricle, however, the sizers may have a general triangular shape. Referring back to Fig. 4a, the length of the sizers along a major axis 403 may be in the range of 2 to 7 cm in length. The length along a minor axis 405 may be 1 to 5 cm in length. The sizers may have a connection 406 for attachment to a handle 404 (Fig. 4b). The sizers 402a-402d can be made out of plastic or stainless steel or any rigid material. Four sizers 402a-402d are illustrated in Fig. 4a, however, any number of sizers in a variety of could be provided.

[0073] Turning now to Fig. 4b, the handle 404 may also be made from stainless steel, plastic or any other suitable material. The handle 404 includes a shaft 408 having a proximal end 410 and a distal end 412. The distal end 412 couples to the connection 406 of the sizers 402a-402d. The proximal end 410 is coupled to a hand grip 414. The hand grip 414 is sized to fit a human hand. Such hand grips are well known in the art. A surgeon may connect any of the sizers 402a-402d to the handle 404. The use of handle

404 with a sizer allows the surgeon to easily estimate the size of the opening to be patched by holding the sizer up to and into the opening. If the sizer is to small, another one may be selected. This process may be repeated until the surgeon feels he has a sizer of the correct shape and size. As will be explained in greater detail below, once the proper size has been determined the sizer may be placed on material and be used as a template to cut the patch 300 to the appropriate size.

[0074] Fig. 4c is a section view illustrating the connection 406 between the distal end 412 of shaft 408 and the sizer 402a. In this embodiment, the connection 406 comprises a circular opening 422. Embedded in the walls of the opening 422 and running through the opening 422 is a rod 420. The rod 420 may be made of surgical stainless steel or another appropriate rigid material. In the illustrative embodiment, the distal end 412 includes a slot 425 with angular walls forming two flanges 423a and 423b. At the base of the slot 425 is a circular groove. The circular grove runs generally parallel to the slot 425 and has an interior diameter slightly larger than the exterior diameter of rod 420. The base of the slot 425 is slightly smaller than the diameter of rod 420. When distal end 412 is inserted into circular groove, flanges 423a and 423b slide over rod 420 until rod 420 is in the circular groove. Thus, flanges 423a and 423b are "snapped" over rod 420, and thus, will keep rod 420 in the cylindrical groove. The sizer 402a may rotate with respect to shaft 408. The sizer 402a may be removed from handle 404 by pulling on the sizer 402a which causes a sufficient amount of force on rod 420 to lift flanges 423a and 423b over rod 420. In other embodiments, connection 406 may be a screw connection.

[0075] In another embodiment, the sizers may have a cutting edge which can be used to cut the patch 300 to the appropriate shape. Turning now to Fig. 4d, a sizer 430 is shown connected to the handle 408. In this embodiment, the sizer 430 may have a ridge 432 concentric to the shape of the sizer 430. The ridge 432 allows a surgeon to accurately estimate the size of the opening by placing the ridge 432 into the opening. The sizer 430 may also have a circumferential flange or lip 434 around the perimeter of the sizer to assist in defining the patch size. The patch will typically be slightly larger than the size of the opening. The width of the lip 434 will preferably have a constant width around its circumference, typically in the range between 5 and 8 centimeters. A cutting edge 434

may also be coupled to the perimeter of the lip. In operation, the surgeon may use the sizer as illustrated in Fig. 4d to estimate the size of the opening, remove the sizer 430 from the handle 408, turn the handle over with respect to the handle 408, and re-attach the sizer 430 to the handle 408. The cutting edge 434 may then be used to cut the patch material to the correct size and shape by pressing the cutting edge into the patch material.

[0076] A set of cutting dies could also be provided which corresponds to the set of sizers. In other words, for each sizer provided in a set of sizers, there would be a corresponding cutting die, sized to be slightly larger than the sizer. Once a surgeon has determined the correct sizer, he could then select the corresponding cutting die and use the cutting die to cut the patch material to the appropriate size. Alternatively, a set of pre-cut patches could be provided, each pre-cut patch corresponding to a particular sizer in the set of sizers. The use of pre-cut patches would eliminate the need to cut the patch material to the required shape. The pre-cut patches may also have pre-printed suture lines which may be used as a guide for the surgeon when attaching the patch to the heart.

[0077] Fig. 4e illustrates an embodiment of a sizer 440 having a protrusion 442 concentric to the shape of the sizer 440. The protrusion 442 may also be used to define a suture line on the patch material by pressing the protrusion 442 against the patch material causing an indentation in the patch material which the surgeon can use as a guide to suture the patch. Turning now to Fig. 4f, which illustrates embodiment of a sizer 450 having a slot or groove 452 concentric to the shape of the sizer. The groove 452 may be used by the surgeon to define a suture line by allowing the surgeon to use a marking instrument, such as a pen, to trace the suture line on the patch material.

[0078] Fig. 4g illustrates yet another embodiment of a sizer. The sizer 460 may be a malleable wire 462 coupled to movable legs 464a-464d (464a and 464b are visible in Fig. 4g). The moveable legs 464a-464d are coupled to a handle 466. The handle 466 includes a shaft 468 having a proximal end 470 and a distal end 472. The distal end 472 couples to the movable legs 464a-464d. The proximal end 470 is coupled to a hand grip 474. The hand grip 474 is similar to the handgrip 414 of Fig. 4b. Fig. 4h is a section view of the sizer 460 cut through the movable legs 464a-464d. The malleable wire 462 may be manipulated by the surgeon into any appropriate shape. Additionally, because one end 466 of the

malleable wire 462 is free to slide past the moveable legs 464a and 464d, the perimeter of the shape formed by the wire may be lengthened or shortened as desired.

Patch Holder

[0079] Turning now to Fig. 5a, there is illustrated a patch holder 500. The patch holder 500 comprises a patch plate 502 coupled to legs 504a-504d (504a and 504b are visible in Fig 5a). The legs 504a-504d are coupled to a handle 506, which is similar to handle 466 discussed above. The patch plate 502 has an adhesive means on side 508, such as an adhesive backing or nylon hooks, which temporarily adheres to the patch. In operation, after a surgeon has constructed the appropriate patch, the surgeon may use patch holder 500 to place the patch into the opening, after suturing has begun, the patch holder may be removed, leaving the patch in place.

Suture Hook

[0080] Turning now to Fig. 5b, there is illustrated a suture hook 520. The suture hook 520 is "L" shaped and made of stainless steel, plastic or another rigid material. The suture hook 520 has a long leg 522 which may be approximately 6 inches long. Coupled to long leg 522, is short leg 524 which may be in the range of one-eighth to one-quarter inch long. The suture hook 520 is adapted to be used to pull up on the sutures in the patch 300 to secure the patch 300 to the heart.

Kit

[0081] In yet another embodiment of the present invention, a kit 600 for surgically reshaping the left ventricle of the heart is illustrated in Fig. 6. The kit 600 may include any of the components discussed above, including: the balloon 201 coupled to the syringe 210, a set of the sizers 402a-402d in various shapes and sizes, a handle 404 to attach to the sizers 402a-402d, material 602 for creating the patch 300 (not shown), the suture hook 520 and, the patch holder 500 (not shown). The components of the kit 600 may be packaged in a sterile manner as known in the relevant art.

OPERATION

[0082] With the primary purpose of restoring the ventricle's size, shape and contour, the intent of the procedure initially is to remove that portion of the wall, which is not capable of contracting. Such portions include the scarred dyskinetic segments, which are easy to see visually, and may also include akinetic segments, which do not contract.

[0083] Referring now to Fig. 7, which illustrates generally a method 700 for performing and using at least one embodiment of the present invention. At step 702, a surgeon determines the appropriate size for the patient's left ventricle based on the patient's height, weight, body surface area and other patient specific conditions (as discussed previously in reference to Fig. 2a). Once the patient's appropriate ventricle size has been determined, at step 704, the surgeon can then select the appropriate volume for the shaping device.

[0084] In step 706, the patient's chest cavity is opened up in a conventional manner. In step 708, an incision is cut into the myocardial wall of the dilated heart. If the surrounding tissue is dyskinetic, it will typically be formed entirely of thin, elastic scar tissue. It is the elasticity of this scar tissue, which causes the detrimental ballooning, or bulging effects previously discussed.

[0085] In step 710, a determination as to where the akinetic portions of the tissue begin and end must be made. The determination between viable and non viable tissue can be made by multiple methods, including: visual inspection, electrical methods, marking with dyes, echocardiography, radionuclear imaging, and palpation of a beating heart.

[0086] The electrical methods might include the use of an electromyogram which detects electrical impulses from active tissue to distinguish between the akinetic and viable tissue. Positron Emission Tomography (PET) scanning, Single Proton Emissions Computer Tomography and Electrical Mapping Electrophysiology are all other examples of a method to determine viable tissue from akinetic tissue with by electrical means. With Electrical Mapping Electrophysiology, a catheter is inserted into the heart to find areas void of electrical activity.

[0087] Marking with dyes can be accomplished by staining the myocardium tissue with a dye that adheres to viable tissue and does not adhere to scar tissue. Triphenyltetrazolium chloride, Tropinin I or T, and Creatine Kinase are all examples of dyes

that perform this marking function.

[0088] Once the extent of the non-viable areas are determined, in step 712, the portion of the tissue in the ventricle and septal walls may be excised from the epicardium from the incision to the borderline separating akinetic tissue from viable tissue. This border between akinetic and viable tissue becomes the preferred location of the patch and forms an imaginary circumferential line between the non viable areas and viable areas of the myocardium.

[0089] In step 714, the preferred location of the patch 300 is been determined relative to the circumferential line. In step 716, a continuous Fontan stitch may be placed in proximity to the line, along the long axis of the heart. The Fontan stitch produces an annular protrusion, which forms a neck relative to the circumferential line. The annular protrusion may be further defined by placing a rim support around its perimeter. This neck initially may have a round circular configuration. A second Fontan stitch may be placed 90 degrees from the initial stitch along the short axis of the heart. Other stitches may be placed as needed to form the heart to the shaping device. The stitch will serve to shape the heart along the short axis of the heart if needed.

[0090] In step 718, the shaping device 200 may then be inserted into the ventricle. The shaping device 200 is then inflated or expanded, the volume of which is equivalent to the appropriate volume of the ventricle for the patient. The shaping device 200 provides the model upon which the ventricle can be shaped and contoured through the use of the Fontan suture in step 720. The Fontan suture may then tightened with the aid of the suture hook 520, in step 722. As the suture or sutures are tightened, the musculature of the myocardium will form the physiologically correct volume, shape and contour over the shaping device. The appropriately oval-shaped opening in the neck defines the area where the patch will be placed. Once the suture is tightened down, the shaping device 200 may be collapsed and removed in step 724.

[0091] The size of the opening in the neck formed by the Fontan stitch will vary from patient to patient. If the patch 300 is used to close the ventricle, the surgeon should determine the size of the patch to be used (step 726). To determine the appropriate size of the patch, the surgeon may connect any of the sizers 402a-402d to the handle 404 to

measure the size of the opening, and thus, the size patch 300 that is needed to fit into the neck formed by the Fontan stitch or stitches. In step 728, the surgeon may then construct a patch. In embodiments with different sizers, once the proper sizer has been selected, the sizer can be placed on the patch and be used as a template to cut the patch 300 to the appropriate size. Alternatively, a surgeon may select a precut patch.

[0092] In a preferred method for placing the patch, continuous or interrupted sutures can be threaded through the rim covered annular protrusion. The rim covering acts as a large continuous pledget along the perimeter. After the patch has been moved into position on the neck, the sutures can be tied, in step 730.

[0093] Alternatively, in cases of extensive nonfibrotic trabecular tissue on the lateral ventricle, another suture method can be placement of mattressed braided sutures over a pericardial strip from outside the ventricle to its interior through the inner oval of the patch. This procedure can be done in conjunction with other procedures such as; Mitral valve repair, ablation of ventricular arrhythmias for treatment of refractory ischemic ventricular tachycardia.

[0094] With the patch suitably placed, in step 732, the suture line can be sprayed with a hemostatic agent or an agent can be applied to achieve better and instantaneous hemostasis. In step 734, the operative site can be closed by joining or folding over the myocardial walls. Care should be taken not to distort the right ventricle by folding the septum wall over the ventricular wall. Alternatively, the lateral wall can be disposed interiorly of the septum wall so a majority of the force on the patch is diverted to the lateral wall. These walls can be overlapped in close proximity to the patch in order to avoid creating any cavity between the patch and the walls.

[0095] When air evacuation is confirmed by transesophageal echo, the patient can be weaned off bypass usually with minimal, if any inotropic support. Decannulasation may be accomplished with conventional methods (step 736).

[0096] As is well known, the human heart contains an electrical conduction system which sends electrical impulses to spark the heart muscle into regular cycles of contraction. This conduction system includes a Sinoatrial node (SA node), Atrioventricular Node (AV node), and Purkinie Fibers which act as conduits for the electrical pulses. The SA node

is located in the right atrium. The electrical impulse leaves the SA node and travels to the right and left Atria, causing them to contract together. This takes .04 seconds. There is now a natural delay to allow the Atria to contract and the Ventricles to fill up with blood. The electrical impulse has now traveled to the Atrioventricular Node (AV node). The electrical impulse now goes to the Bundle of His, then it divides into the Right and Left Bundle Branches where it rapidly spreads using Purkinje Fibers to the muscles of the Right and Left Ventricle, causing them to contract at the same time.

[0097] Because ventricular restoration may compromise the conduction system due to the fact that a ventricle portion has been severed or excluded, the pacing or rhythm of the impulses between the right and left ventricles of the heart may get out of synchronization after ventricular restoration. This asynchronous pacing contributes to a reduced output by the left ventricle. Thus, restoring or assuring synchronization would assist the reconstructed left ventricle to maximize the output of the left ventricle. Synchronization may be restored or controlled by implanting a pacemaker or a Biventricular pacing device ("BVP") before closing the chest cavity.

[0098] A pacemaker comprises: (1) an implantable controller that sets the heart rate to the desired interval, and (2) two leads that deliver electrical impulses to specific regions of the heart (i.e., one lead is placed in the right atrium and the second lead in right ventricle) to artificially cause contractions of the ventricle at the appropriate time and synchronization. In contrast, BVPs have a third lead designed to conduct signals directly into the left ventricle. When using a BVP, one lead is placed in the right atrium, the second lead in right ventricle and third lead is placed to pace the left ventricle (i.e., in a tributary of the coronary sinus in the left ventricle). Thus, with a BVP, simultaneous electrical impulses are given to both left and right ventricles so the time delay in traveling of electrical impulse is significantly reduced which aids in restoring the normal physiology of the heart and improves the pumping action of the heart.

[0099] Pacemakers and biventricular pacing devices are available from Medtronic, Inc. (Minneapolis, Minnesota), Guidant Corporation (Menlo Park, California), and St. Jude Medical Inc. (St. Paul, Minnesota).

[0100] The mortality associated with ventricular restoration is primarily from sudden

death caused from extremely fast arrthymias. The higher risk of arrthymias may be caused from the removal of a portion of the left ventricle. This risk may be prevented by implanting a defibrillator at the time of the ventricle restoration. The automatic implantable cardioverter / defibrillator is commonly referred to as an AICD. The AICD is a device that is similar to a pacemaker, but continuously monitors the heart rhythm. If the AICD detects an abnormally fast or slow heart rhythm, it either electrically paces the heart very fast or delivers a small electrical shock to the heart to convert the heart rhythm back to normal.

[0101] Some BVP devices have defibrillators built into the circuitry that controls the pacing. Implanting a bi-ventricular pacing device with defibrillator after surgical ventricular restoration will not only optimize the output of the ventricle but also prevent many sudden deaths.

[0102] After a BVP has been installed in step 738, closure of the chest cavity may be accomplished in step 740 by conventional methods.

[0103] It is further understood that other modifications, changes and substitutions are intended in the foregoing disclosure and in some instances some features of the disclosure will be employed without corresponding use of other features. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the scope of the disclosure.